

Summary Information

DEC 07 2007

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K073157**

- 1. Submitter** Ortho-Clinical Diagnostics, Inc.
name, 100 Indigo Creek Drive
address, Rochester, New York 14626-5101
contact (585) 453-4041

Contact Person: Marlene A. Hanna
- 2. Preparation date** Date Special 510(k) prepared: November 7, 2007
- 3. Device name** Trade or Proprietary Name:
VITROS Chemistry Products K⁺ Slides
Common Name: Potassium test
Classification Name: Potassium test system (21 CFR 862.1600)

VITROS Chemistry Products Calibrator Kit 2
Common Name: calibrator
Classification Name: Calibrator (21 CFR 862.1150)
- 4. Predicate device** The VITROS Chemistry Products K⁺ Slides (modified) and VITROS Chemistry Products Calibrator Kit 2 are substantially equivalent to the VITROS Chemistry Products K⁺ Slides (current slide) and VITROS Chemistry Products Calibrator Kit 2. The FDA cleared the VITROS Chemistry Products K⁺ Slides on May 7, 1996 (K961115) under the product name EKTACHEM Clinical Chemistry Slide Potassium (K⁺). With the purchase of KODAK Clinical Products Division by Johnson and Johnson, the product branding was later revised to VITROS Chemistry Products K⁺ Slides. The most recent FDA clearance for the VITROS Chemistry Products Calibrator Kit 2 was July 20, 2007 (K071801).

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5. Device Description	<p>The VITROS K⁺ assay is performed using the VITROS Chemistry Products K⁺ Slide and the VITROS Chemistry Products Calibrator Kit 2 on the VITROS Chemistry Systems. The VITROS K⁺ Slide is a multilayered, analytical element coated on a polyester support that uses direct potentiometry for measurement of ionic potassium. All reactions necessary for a single quantitative measurement of potassium take place within the multi-layered analytical element of a VITROS Chemistry Products K⁺ slide. The slide consists of two ion-selective electrodes, each containing valinomycin (an ionophore for potassium), a reference layer, and a silver layer and a silver chloride layer coated on a polyester support.</p> <p>VITROS Chemistry Products K⁺ Slides use ion-selective electrodes for potentiometric measurements of ionic potassium. Ionic potassium determinations are made by simultaneously depositing 10 μL each of a reference fluid and a sample fluid on separate halves of the VITROS Chemistry Products K⁺ slide. The electrode receiving the reference fluid is identified as the reference electrode. A paper bridge connects the reference electrode and the indicator electrode, which receives the sample fluid. A stable liquid junction between the two fluids is formed in the paper bridge in approximately 20 seconds. The potassium ions in the tested reference and sample fluids migrate to the silver/ silver chloride layers and establish equilibrium.</p> <p>After a two minute incubation period, the electrometer in the VITROS Chemistry System measures the potential difference between the reference and indicator electrodes. Each electrode responds to the activity of potassium ions in the respective fluids to produce a potential for the concentration cell. The VITROS Chemistry System's microcomputer uses this measurement and the stored calibration parameters to determine the concentration value of the potassium ion in the sample fluid. The test result is reported in millimoles per liter (mmol/L).</p> <p>VITROS Chemistry Products Calibrator Kit 2 contains four levels of lyophilized standards with corresponding diluents. The standards are prepared from processed bovine serum to which bovine cholesterol, chicken egg yolk, inorganic salts, electrolytes, buffers, stabilizers, and preservatives have been added. The companion diluents are prepared from processed water to which inorganic salts have been added. In addition, Calibrator 4 Diluent contains 0.5 M diethylaminoethanol and 0.01 M (ethylenedinitrilo) tetraacetic acid.</p> <p>The VITROS System and reagents are designed specifically for use with the VITROS Chemistry Products range of products.</p>
6. Device intended use	<p>VITROS Chemistry Products K⁺ Slides For <i>in vitro</i> diagnostic use only. VITROS K⁺ Slides quantitatively measure potassium (K⁺) concentration in serum, plasma, and urine.</p> <p>VITROS Chemistry Products Calibrator Kit 2 For <i>in vitro</i> diagnostic use only. VITROS Calibrator Kit 2 is used to calibrate the VITROS Chemistry Systems for the quantitative measurement of CHOL, Cl⁻, ECO2, HDLC, K⁺, Na⁺, and TRIG.</p>

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7. **Comparison to predicate device** The VITROS Chemistry Products K⁺ Slide (modified) and VITROS Chemistry Products Calibrator Kit 2 are substantially equivalent to VITROS Chemistry Products K⁺ Slide and VITROS Chemistry Products Calibrator Kit 2, which were Cleared by the FDA for *in vitro* diagnostic use.

VITROS Chemistry Products K⁺ Slide: (K961115, cleared May 7, 1996)
VITROS Chemistry Products Calibrator Kit 2: (K071801, cleared July 20, 2007).

Table 1 lists the characteristics of the tests performed using the VITROS K⁺ Slide (modified) and the VITROS K⁺ Slide (current).

Table 1. List of VITROS Chemistry Products K⁺ Slide Characteristics: Comparison to Predicate Device

Device Characteristic	New Device VITROS Chemistry Products K ⁺ Slide (Modified)	Predicate Device VITROS Chemistry Products K ⁺ Slide (Current)
Intended Use	No Change.	For <i>in vitro</i> diagnostic use only. VITROS K ⁺ Slides quantitatively measure potassium (K ⁺) concentration in serum, plasma, and urine.
Fundamental scientific technology	No Change.	Dry, multilayered slide utilizing direct potentiometry
Sample type	No Change.	Serum, plasma, urine
Instrumentation	VITROS 250, 950 and 5,1FS Series Analyzers. The 550 and 750 analyzers will not be supported by OCD as of January 1, 2008.	VITROS 250, 550, 750, 950 and 5,1FS Series Analyzers
Reactive Ingredients per cm ²	No Change.	Silver 0.4 mg and silver chloride 0.2 mg; sodium chloride 0.2 mg; potassium chloride 63 µg, valinomycin 55 µg.
Other Ingredients	Binders, plasticizers, stabilizer, surfactants and nickel-chromium.	Binders, plasticizers, stabilizer, surfactants and nickel.
Composition of ISE baseweb* component	Ag/AgCl concentration: No change Nickel Stripes: NiCr (80% Nickel, 20% Chromium)	Ag/AgCl concentration: Silver 0.4 mg and silver chloride 0.2 mg Nickel Stripes: Ni (99+% Nickel)
Manufacturing Process of the ISE baseweb* (Ag/AgCl and Support Layers of the K ⁺ Slide)	Magnetic sputter deposition	Electron beam evaporation

* ISE (Ion-Selective Electrode) baseweb= Polyethylene terephthalate film (substrate used for metallized film) coated with silver (Ag)/ silver chloride (Ag/Cl) and striped with nominal nickel (Ni) stripes. The “ISE baseweb” refers to the Ag/ AgCl with nickel stripes layer and support layer of the VITROS Chemistry Products K⁺ Slide.

NOTE: No modifications were made to VITROS Chemistry Products Calibrator Kit 2. VITROS Calibrator Kit 2 is included in this submission, since the VITROS K⁺ Slide is used in conjunction with VITROS Calibrator Kit 2, and together are considered to be to the “VITROS K⁺ assay”.

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8. Conclusions The information presented in the premarket notification demonstrates that the performance of the VITROS Chemistry Products K⁺ Slides (modified) for use with human serum, plasma, and urine is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured potassium values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS Chemistry Products K⁺ Slides (modified) for use with human serum, plasma, and urine is safe and effective for the stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ortho-Clinical Diagnostics, Inc.
c/o Ms. Marlene Hanna
Regulatory Affairs Manager MC00881
100 Indigo Creek Drive
Rochester, New York 14626-5101

DEC 07 2007

Re: k073157

Trade/Device Name: Vitros Chemistry Product K+ Slides and
Vitros Chemistry Products Calibrator Kit 2

Regulation Number: 21 CFR 862.1600

Regulation Name: Potassium Test System

Regulatory Class: Class II

Product Code: CEM, JIX

Dated: November 07, 2007

Received: November 08, 2007

Dear Ms. Hanna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

Indication for Use

510(k) Number (if known): K073157

Device Name: VITROS Chemistry Products K⁺ Slides

Indication For Use: For *in vitro* diagnostic use only. VITROS K⁺ Slides quantitatively measure potassium (K⁺) concentration in serum, plasma, and urine. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases and conditions characterized by low or high blood potassium levels.

Prescription Use X And/Or
(21 CFR Part 801 Subpart D)

Over the Counter Use ____.
(21 CFR Part 801 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indication for Use

510(k) Number (if known): K073157

Device Name: VITROS Chemistry Products Calibrator Kit 2

Indication For Use: For *in vitro* diagnostic use only. VITROS Calibrator Kit 2 is used to calibrate the VITROS Chemistry Systems for the quantitative measurement of CHOL, Cl⁻, ECO2, HDLC, K⁺, Na⁺, and TRIG.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson
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